

REMARKS/ARGUMENTS

In response to the Office Action mailed May 20, 2008 and the Advisory Action mailed July 31 2008, Applicants amend their application and request continued examination. In this Amendment, no claims are cancelled, and, claims 24 and 25 are added.

This Amendment

A number of claims are amended with respect to matters of form, particularly in response to the claim objections to claims 7 and 23. Specifically, the words “for containing a medicinal product” are removed from each of the independent claims because the language is unnecessary and only describes an intended use of the reservoir. Claims 7 and 23 are corrected in response to the claim objection. The two external pads referred to in those claims correspond, in the described embodiments of the invention, to the pads 14. Those pads clearly close the first chamber, not the second chamber, when the lid of the claimed device is closed. It is believed that the Examiner perceived the error in these two claims, leading to the claim objection that is corrected here.

Two new claims are added in this Amendment, claims 24 and 25. Claim 24 is a dependent claim depending from claim 2 and further describes the bearing upon and pressing against lateral faces of the supporting base by lateral faces of the two pads, when the lid of the claimed device is closed. This claim is clearly supported by the disclosure of the patent application, in the substitute specification, in the paragraph that begins at page 8 in line 23. New claim 25 is an independent claim that encompasses all of claim 1 and part of claim 2. The new claim is fully supported by those other claims.

The Advisory Action

In the Advisory Action mailed July 31, 2008, the Examiner explained her position with respect to maintaining the prior art rejection. Applicants respectfully and vigorously disagree with every point made by the Examiner. It is for that reason, that a further attempt, short of an appeal, is being made to urge the allowance of the pending claims.

Applicants agree with the Examiner that both the primary and secondary references describe "catheter securement devices." However, Applicants do not agree that it would have been obvious to excise the "wings" from Bierman '291 and to incorporate those wings, an incorporation which is mechanically impossible, into Landuyt. The former arguments concerning this error are re-presented below. Further, it is not, contrary to the Examiner's position, "immaterial" that Bierman '291 employs an adhesive providing a tension force holding two elements in place with respect to each other because, as previously explained and repeated below, in the invention a differently directed and produced force is employed to hold the catheter in place.

The assertion that the argument that no structure in Landuyt can apply a compressive force to the wings is irrelevant, because no compressive force is required by the claims, is false. Applicants respectfully direct the Examiner's attention to each of the independent claims. Each of those claims describes, in one form or another, that when the lid is closed, the pads "bear on the wings, holding the supporting base of the catheter *against* a bottom wall of the second chamber." Compression between two elements means that the elements are pushed against each other. That compression is precisely described in the patent application, for example in the substitute specification at page 8 in the paragraph beginning in claim 23, and explicitly in the claims. It appears that the Examiner has not given appropriate attention to each word of the claims, as required in the U.S. examination practice. Therefore, Applicants ask for reconsideration and, if the Examiner maintains her position, a clear explanation as

to why the language of the independent claims quoted above does not describe the application of a compressive force to the wings.

For the reasons presented below, Applicants likewise assert that the hypothetical modification of Landuyt with Bierman '291, while, at best, implausible, does not produce the structure of the claimed invention. Only hindsight knowledge of the invention provides the basis for speculating on what might be the result if an attempt were made to modify Landuyt with Bierman '291. That kind of reconstruction has never been recognized as providing a basis for establishing *prima facie* obviousness.

Prior Art Rejections

Most of the pending claims, and the three examined independent claims, claims 1, 22, and 23, were rejected as obvious over Landuyt (U.S. Patent 6,387,076) in view of Bierman (U.S. Patent 7,153,291, hereinafter Bierman '291). This rejection is respectfully traversed.

The Claimed Invention

The subject matter of the claimed invention and of Landuyt and Bierman '291 are the same. However, no matter how one attempts to modify Landuyt with Bierman '291, the claimed invention cannot be produced.

The invention concerns a device for affixing a catheter to a patient. The catheter enters the body of the patient. The device holds the catheter in place and permits connection of various lines to the catheter for the infusion of medicinal products or other materials into the patient. The claimed invention actually encompasses at least part of the catheter structure. The catheter includes a supporting base having wings that extend from opposite lateral faces of the supporting base, according to each of the four pending independent claims. The claimed device includes a lid that closes on a housing so that the catheter is within a volume defined by the housing and the lid, when the lid is closed.

According to all four independent claims, the lid includes, on an internal face, two pads which penetrate into a part of the housing “and respectively bear on the wings,” thereby “holding the supporting base of the catheter against the bottom wall of the second chamber” of the housing. In other words, the pads press against the wings, stabilizing the catheter and holding it in position. At least this feature is not disclosed nor suggested in either of Landuyt or Bierman ‘291 and cannot be produced by any modification of Landuyt with Bierman ‘291.

Dependent claim 2 and, particularly, its new dependent claim 24, describe a further arrangement in which a compressive force is applied to stabilize the catheter. That additional compressive force is applied by the opposing oblique faces of the pads to the opposing oblique faces of the supporting base. No corresponding structure is disclosed or suggested in any potential modification of Landuyt with Bierman ‘291.

Response to Prior Art Rejections

As an initial matter, it is improper to attempt to modify Landuyt with Bierman ‘291. Landuyt describes an enclosure for a tube of a catheter. A tube 4 is, in Landuyt, placed within two V-shaped notches that are spaced from each other and then clamped in position by a plurality of “teeth” or “vanes” that project from the lid, transverse to the direction of the tube 4. It is apparent to even an unskilled person that those teeth 35, while possibly restraining the tube 4 by clamping the tube 4 against a floor including protrusions 15, tends to pinch and close that tube 4. Thus, the structure of Landuyt does not even appear to be well suited for the function for which it is intended.

Bierman ‘291 describes a tube leading to a catheter that, like the tube or catheter structure of the claimed invention, includes a pair of wings 18 that extend laterally from a conical receptacle 14 that has a threaded rim 16 for connection of a tube feeding a product to be infused through the catheter.

In Bierman ‘291, the positioning of the fitting 12, which includes the wings 18 with through-holes 20, is mounted on a retainer 30 that includes two posts 28. The

posts extend through the holes 20 of the wings. However, as apparent to anyone of reasonable skill, insertion of the posts 28 within the holes 20 would not be sufficient to hold the fitting 12 in place. Thus, the fitting is brought into contact with an adhesive member 24. The adhesive of that member 24 holds the fitting 12 against the retainer 30 and resists removal of the fitting by pulling the fitting toward the retainer 30. The post and hole arrangement prevents wiggling of the fitting 12 with respect to the retainer 30 and the adhesive prevents the lifting of the fitting 12 from the retainer 30.

Landuyt and Bierman '291 are entirely different in how each holds the tube or fitting or catheter in place. In Landuyt, as already described, the tube 4 is held in place with a clamping, compressive force applied from two different sides of the tube. The teeth 35 apply pressure from one side of the tube and the floor with the protrusions 15 provides force against the other side of the tube 4.

By contrast with Landuyt, in Bierman '291, the fitting 12 is held in place by tension, not compression. The adhesive on the member 24 pulls the fitting 12 against the retainer 30, quite unlike and even contrary to the arrangement provided by Landuyt. Thus, because different techniques, functioning in opposite ways, are employed to hold in place the tube of a catheter in Landuyt and in Bierman '291, there can be no suggestion for modifying one of those devices with the other.

The fundamental advantage of Landuyt is entirely inconsistent with Bierman '291, further showing that the hypothetical modification of Landuyt with Bierman '291 is not reasonable. As described in column 4 of Landuyt, and even in its claim 1, an important feature of the catheter retainer of Landuyt is that it may be removed from the patient without disturbing the tube 4. This result is achievable because, upon opening of the lid, the compressive force applied to the tube 4 is relieved. Since the tube 4 is not fastened in a permanent way to the Landuyt device, the device can be removed without disturbing the catheter. By contrast, in Bierman '291, the catheter is adhered to the retainer 30. Thus, it is impossible to disengage the device of Bierman '291, including the retainer 30, from elements of the catheter without disturbing the

catheter. For that reason alone, one of skill in the art would not seek to modify Landuyt with parts of Bierman '291 that are contrary to the fundamental objective of Landuyt.

Even if there were some basis for modifying Landuyt with Bierman '291, the result could not be the invention as described by the pending independent claims. There is no teaching in those references that any compressive force should be applied to the catheter wings. In making the rejection, the Examiner acknowledged that the tube 4 of Landuyt lacks any wings, like the wings described in each of the independent claims. For that feature of the invention, reliance was placed on Bierman '291. However, in the invention, unlike Bierman '291, pads on the lid of the claimed device respectively bear on those wings, when the lid is closed, holding the wings in place. Those pads apply a compressive force to the wings, to hold the catheter in place. No compressive force is applied to the wings 18 in Bierman '291. Moreover, there is not even any structure in Landuyt that could apply a compressive force to the wings. The hypothetical modification cannot meet any pending claim.

In order to apply a compressive force to the wings 18 of Bierman '291, one would have to remove the posts 28 from Bierman '291 or provide a structure accommodating those posts. Such a structure would have to be generally parallel to the catheter direction, i.e., the direction of the tube 10, extending outwardly from the conical receptacle 14 of Bierman '291. The teeth 35 of Landuyt cannot provide that structure. Those teeth are perpendicular to, not parallel to, the tube 4 in Landuyt. Rotating those teeth 90° would make Landuyt even more ineffective in achieving its goal, namely clamping the tube 4, than the arrangement shown in Landuyt. Such spaced apart teeth, extending parallel to the tube 4, could even crush the tube, preventing fluid flow, or straddle the tube, allowing the tube to slide along its longitudinal axis.

Since these hypothetical modifications of Landuyt with Bierman '291 would make Landuyt useless for its intended purpose, the proposed modifications cannot establish obviousness, as explained in MPEP 2143.01 V.

Even if the teeth 35 of Landuyt were changed in direction by 90°, how could those teeth accommodate the conical receptacle 14 of the Bierman '291 catheter? Eliminating some of those teeth in favor of others is still a further unjustified hypothetical modification of Landuyt. Finally, how could wings be added to the simple lumen 4 of Landuyt? Clearly, the attempt to add a winged catheter to Landuyt has to be based upon knowledge of the invention since the substitution would not be operable in Landuyt.

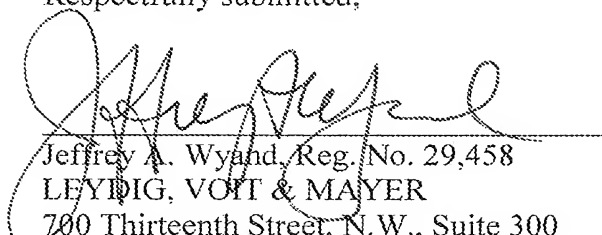
There simply is no basis for the several modifications that would be required with respect to both Landuyt and Bierman '291 to produce the invention as defined by all four pending independent claims. *Prima facie* obviousness of those claims cannot be established from those two publications.

For all of the foregoing reasons, the rejection of claims 1, 2, 4, 5, 7-10, 14, 15, 22, and 23 as obvious over Landuyt in view of Bierman '291 is legally and factually erroneous and should, upon reconsideration, be withdrawn.

Applicants note that claims 6, 11, and 12 were rejected as obvious based upon the purported modification of Landuyt with Bierman '291 and in view of tertiary references. However, it is apparent that the rejections of those claims are premised upon the rejection of claim 1, from which those claims ultimately depend. Because that fundamental rejection has been shown to be erroneous, further discussion with regard to the rejection of claims 6, 11, and 12 is neither required nor provided.

Reconsideration and allowance of all pending claims are earnestly solicited.

Respectfully submitted,



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